Endovascular repair of thoracic aortic lesions with the Zenith TX1 and TX2 thoracic grafts: Intermediate-term results

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Purpose: **This prospective study was designed to assess the technical success and outcome after patients with thoracic aortic pathology at high risk for conventional therapy were treated with the Zenith TX1 and TX2 endovascular graft.**

Methods: **Between 2001 and 2004, patients at high risk for conventional surgical therapy presenting with chronic aortic dissections, thoracic aneurysms, or aortobronchial or aortoesophageal fistulas were treated with a single- or multiple-piece endovascular grafts. Surgical modification of proximal or distal fixation sites was performed when necessary to establish adequate regions for device landing zones. Follow-up studies included radiographic evaluation before discharge and at 1, 6, 12, and 24 months. Aortic morphologic characteristics were determined by using three-dimensional imaging studies and centerline of flow measurements. Statistical analyses were performed with Kaplan Meier analysis to assess survival, factors predictive of poor outcome, and morphologic changes, including sac shrinkage.**

Results: **A total of 100 patients (42% women) were treated, including 81 aneurysms, 15 aortic dissections (with aneurysms), 2 patients with fistulous connections (1 aortobronchial and 1 aortoesophageal), 1 subclavian artery aneurysm, and 1 aortic rupture. Mean follow-up and aneurysm size were 14 months and 62 mm, respectively. Most patients (55%) had undergone prior aortic aneurysm repair. Surgical modifications were required to create adequate implantation sites in 29% patients, including 14 elephant trunk/arch reconstructions, 18 carotid-subclavian bypasses, and 4 visceral vessel bypasses. Iliac conduits were required in 19 patients. Overall mortality was 17%, and aneurysm-related mortality was 14% at 1 year. Sac regression (>5 mm maximum diameter decrease) was observed in 52% and 56% at 12 and 24 months. Growth was noted in one patient (1.6%) at 12 months. Endoleaks were detected in eight patients (8.5%) at 30 days and three patients (6%) at 12 months. Secondary interventions were required in 15 patients. Migration (>10 mm) of the proximal or distal stent was noted in three patients (6%) (two proximal and one distal), none of which required treatment or resulted in an adverse event.**

Conclusions: **Acceptable intermediate-term outcomes have been achieved in the treatment of high-risk patients in the setting of both favorable and challenging anatomic situations with these devices. The complexity of the patient population, in contrast to endovascular infrarenal repair, attests to the differences in the pathophysiology aortic disease in the anatomic beds. (J Vasc Surg 2005;41:589-96.)**

Endovascular thoracic aortic aneurysm repair is a natural progression of technology initially introduced in 1991[1,2] for aneurysm repair. Several reports of early experiences with homemade and commercially manufactured devices have been authored.[3-5] Indications for endovascular treatment of thoracic pathology have included aortic diverticulum, aneurysms, acute dissections, chronic dissections, and aortobronchial fistulae. However, the guidelines for repair of thoracic diseases are less defined than infrarenal aneurysms.

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Problems similar to those encountered with infrarenal endovascular grafts, including endoleak, migration, rupture, and an increased need for secondary interventions, also plague the thoracic endovascular procedures, and device stability and integrity may be more hampered by the inherently challenging anatomy and relatively greater hemodynamic forces within the aorta. The Zenith thoracic device (Cook, Blooomington, In) described in this report originated from an international collaborative effort. The most recent version of this device is undergoing a United States phase II multicenter trial and is commercially available in Europe, Australia, and Canada.

METHODS

This study was performed under the guidance of a sponsored investigational device exemption that began in February 2001, with prospective data collection continuing through April 2004. All patients enrolled were considered to be at high risk for a conventional surgical repair, had agreed to participate in the study, and signed an informed consent form approved by the institutional review board. Inclusion criteria are listed in Table I.

Table 1. Inclusions criteria for patient enrollment

	Inclusion criteria
Pathology	Thoracic aneurysm >5cm or anuerysm with a history of rapid growth
	Subclavian aneurysm >2.5cm
	Chronic aortic dissection with aneurysm >5 cm or rapid growth
Comorbidities	Life expectancy >2 years
	High-risk for open surgical repair*
	Absence of an uncorrectable coagulopathy
	Absence of allergy to stainless steel or polyester
	Absence of a serious groin infection
	Absence of systemic sepsis
Anatomic	
Proximal and distal necks	Length >10mm
	Diameter ≤40 mm
Access	Iliac arteries >7mm in diameter†
	Absence of severe angulation†

*This was a relatively subjective assessment of comorbid conditions including cardiac, pulmonary, renal, prior surgical procedures, and anatomic complexity. In general, patients were seen by a cardiothoracic surgeon as well as a vascular surgeon prior to repair to determine open surgical risk.
†The use of an iliac conduit was acceptable to treat patients with iliac disease that did not meet the stated inclusion/exclusion criteria.

Device design. Implants were constructed from stainless steel Z-stents (Terumo-Vascutek Inc, Glasgow, Scotland) attached to a conventional thickness polyester fabric with ethibond sutures in an attempt to minimize intercomponent movements. Two primary device options were available throughout the study (Fig 1).

The proximal fixation system for both TX1 and TX2 devices consists of an internal Gianturco Z-stent with a series of 5-mm long barbs caudally oriented that extend through the polyethylene terephthalate fabric in a staggered configuration. The distal fixation system employs an uncovered Gianturco Z-stent with 5-mm barbs staggered and cranially oriented. The diameters available were 22 mm to 42 mm in 2-mm increments, and the lengths were 77 mm to 220 mm.

The delivery system incorporated a means to afix the proximal and distal portions of the endografts to a central core (Fig 2). Thus, deployment of the entire segment of the covered stents without the induction of hypotension or bradycardia was possible, while to a certain extent, eliminating any rushed deployment and preserving the ability to reposition the device during the deployment process. A 20F system was used for devices <34 mm in diameter, and a 22F system was required for the rest of the devices.

The delivery system underwent several changes during the course of the study, including the addition of a precurved proximal portion to assist with manipulation through the aortic arch and alterations to the trigger wire systems (the mechanism used to attach the device to the delivery system). The later change involved conversion of the trigger wires from a stainless steel design, where tortuous cases caused some kinking, to a series of nitinol wires. In addition, the proximal trigger wire was supplemented with two additional wires, making a triad of wires to properly constrain and stabilize the device during deployment. A further change, intended to remove any possibility of sheath kinking, was changing the sheath material from a standard expanded polytetrafluoroethylene (PTFE) design to a braided sheath.

Preoperative imaging information was obtained from high-resolution spiral computed tomography CT) scans evaluated using three-dimensional (3D) technology (Seimens Leonardo Workstation and TeraRecon 3D software programs). Aortic diameters were computed at the desired proximal and distal fixation sites. Lengths were calculated using centerline of flow algorithms, unless in straight segments. Angiography was used selectively.

Oversizing ranged from 10% to 25%, and graft lengths were intended to extend 3 cm (if possible) into the normal aorta proximal and distal to the offending pathology. Modular devices were designed to have an extensive degree of overlap (>5 cm). In this setting, the proximal component was designed to terminate at the distal end of the aneurysm or immediately proximal to any significant aortic tortuosity. The distal component then extended from the proximal portion of the aneurysm through the distal sealing zone.

Implantation procedure. Procedures were performed in an endovascular operating room with a fixed imaging system (Siemens Angiostar or Axiom Artis FA). General, regional, or local anesthesia was used at the discretion of the anesthesiologist, patient, and surgeon. Spinal drains were used selectively when the perceived risk of paraplegia was high, and when inserted, to administer regional anesthetics. Femoral access was established after arterial exposure with an oblique incision in conjunction with a counter incision. A second access site was used in all patients and included the left brachial artery for some proximal aneurysms, the right brachial artery in the setting of elephant trunk completion procedures, and the contralateral femoral in the setting of most thoracic lesions. Patients received heparin anticoagulation.

Endovascular grafts were inserted over a stiff wire (Lunderquist or Amplatz Wire, Cook, Inc), and deployed without specific manipulation of the blood pressure or heart rate. A balloon was selectively used to achieve appropriate device conformity at the sealing locations. Completion angiography was performed using a rapid frame rate (6 to 7.5 frames per second) to differentiate cardiac motion from contrast extravasation.

Follow-up. The follow-up protocol required patients to undergo CT scanning and chest radiography before discharge, at 30 days, and at 6, 12, and annually thereafter. Physical examinations, basic laboratory studies, and ankle brachial indices were also obtained at the follow-up visits. Image analysis was conducted on work stations. Morphologic changes are reported in adherence to the reporting standards for endovasuclar aneurysm repair.

Data definitions and statistical analysis. Technical success was defined as placement of a patent endoprosthesis in the desired location in the absence of a type I or III

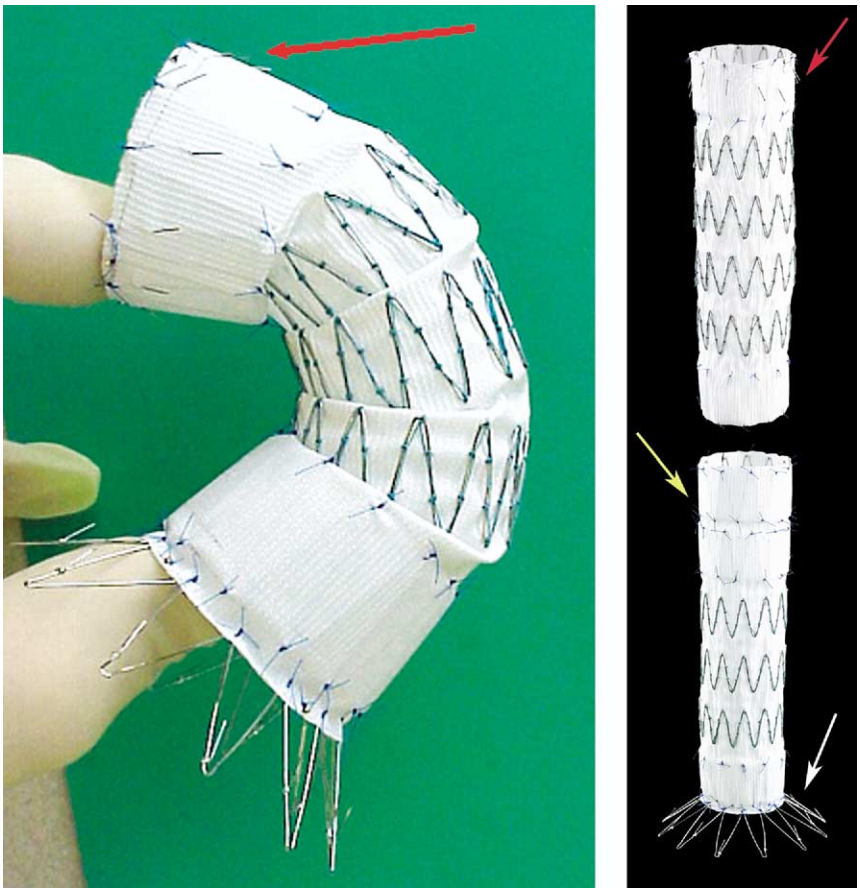

Fig 1. The implant components of Zenith TX1 and TX2 systems. **A,** The TX1 has the proximal and distal fixation systems on a single component. **B,** The TX2 fixation system is split between a proximal (TX2P) and distal (TX2D) component, with an intended minimum of a two-stent overlap between them. Note the presence of caudally oriented barbs on the TX1 device and the proximal component of the TX2 system *(red arrows)*. The proximal component of the TX2 system has no distal barbs and terminates distally in an internally mounted sealing stent. The distal TX2 component has a two-stent overlap zone where the stents are sutured to the internal portion of the polyethylene terephthalate material (*yellow arrow*). Distally, this piece has an uncovered stent with cranially oriented barbs *(white arrow)* in an effort to prevent proximal migration of the distal sealing stent. Fundamentally, the TX1 device was used to treat focal aortic pathology, whereas more diffuse disease was treated with a TX2 device.

endoleak (detected angiographically). Data regarding aneurysm size, endoleaks, mortality, and other descriptive characteristics are reported in compliance with the most recent endovascular aneurysm repair reporting standards document.[6]

RESULTS

A total of 100 patients were treated (97 based on the investigational device exemption inclusion criteria and 3 on a compassionate-use basis), with a mean age of 69 years (range, 37 to 86). The breakdown of etiology of aortic pathology and type of device used are summarized in Table 2. Mortality, diameter changes, and migration are categorized by pathology and listed in Table 3 and Fig 3. Observed endoleaks are categorized in Fig 4.

Technical success was achieved in 87.6% patients who met the study inclusion criteria and in all patients treated on a compassionate-use basis. Aneurysm-related death occurred in 13 patients (7 ≤30 days of the procedure, 3 deaths were attributed to the aneurysm but yet were unrelated to the acute procedure). Three patients died from unrelated causes (see Table IV).

Neurologic complications. Spinal cord ischemia was suspected in six patients, and complete and permanent paraplegia developed in two. One case of paraplegia was attributed to distal embolization that resulted in multisystem organ, and the patient ultimately died. The other paraplegic patient had extensive aortic coverage (midarch after a carotid subclavian bypass up to the celiac artery) in the setting of a single hypogastric artery.

Three cases of paraperesis were noted, two of which were asymmetric (involving only one leg). All paraperetic patients recovered substantially before hospital discharge. A single case of late paraperesis occurred 1 year after device

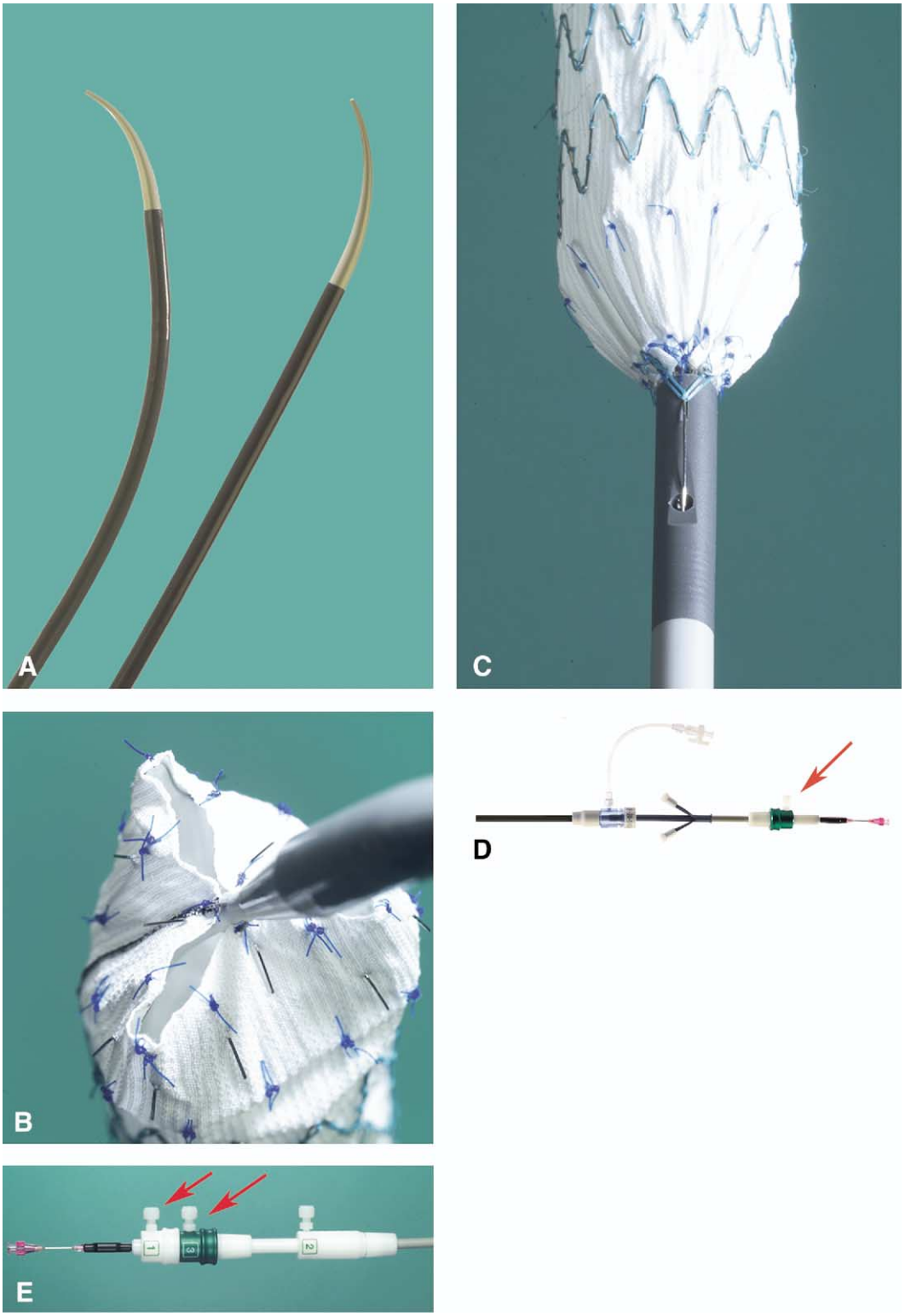

Fig 2. The delivery system consists of **(A)** a tapered tip with a gradiant stiffness that may be precurved to fit into the aortic arch, a polytetrafluoroethylene sheath, and a handle. Three nitinol wires attach the proximal component to the delivery system. A single wire, in conjunction with the bottom cap (which constrains the distal uncovered stents with crainially oriented barbs), attaches the distal portion of the device (**B** and **C**, respectively). The delivery system for the proximal piece of the TX2 has only one trigger wire. **D**, After exposure of the prosthesis by sheath withdrawal, the single trigger wire is released *(red arrow)* allowing expansion of the proximal stent and barbs. **E,** The TX1 delivery system and distal component of the TX2 delivery system contain trigger wires for both the proximal and distal barbed regions *(red arrows)*.

Table II. Demographic and procedural information

	Thoracic aneurysm	*Chronic dissection with aneurysm*	*Other**
Number of patients	81	15	4
Age (years)	71	54	71
Male sex	56%	73%	50%
Prior aortic repair	58%	27%	75%
Mean aneurysm size(mm)	64	55	68
Surgical modification	40%	0%	75%
Proximal neck	35%	0%	50%
Distal neck	5%	0%	0%
Conduit	24%	0%	0%
TX1 device	56%	67%	100%
TX2 device	44%	33%	0%
Operative time (min)	143	102	138
General anesthesia	12%	0%	50%
Regional anesthesia	88%	100%	50%
Fluoroscopy time (min)	18	15	13
Contrast dose (mL)	135	121	107
Estimated blood loss (mL)	490	168	500
Spinal drain	85%	82%	75%
Acute spinal cord ischemia	7.4%† 6 (2)	0%	0%
Acute CVA	2.5%	0%	25%

CVA, Cerebrovascular accident.
*Includes 1 subclavian aneurysm, 1 aortobronchial fistula, 1 aortoesophageal fistula, and 1 thoracic rupture.
†Expressed as the total number of cases including temporary paraperesis. Peremanent paralysis numbers are deonted within the parentheses.

implantation following the development of an iliac crest fracture with presumed hypotension. The definitive association of the latter four cases with a spinal perfusion defect remains in question.

Cerebral ischemic/embolic infarcts occurred in three patients, all of whom had aneurysms of the arch or proximal descending thoracic aorta. Despite the absence of detectable embolic events on cerebral angiography in two of the three cases (the last did not undergo a cerebral angiogram), the CT scans all demonstrated embolic patterns. Two strokes occurred acutely during the procedure in the absence of a general anesthetic and occurred at the time of balloon inflation within the aortic arch.

Secondary procedures. Fourteen patients underwent secondary procedures. The recurrance of an aortobronchial fistula required coverage of more proximal aorta 1 year after the initial prosthesis was placed for an initial aortobronchial fistula. To treat this patient, a carotid-carotid-subclavian bypass was performed, and an expanded PTFE prosthesis (W.L.Gore, Flagstaff, Ariz) was placed with the intention of improving the microbial resistance characteristics. The patient has done well through 3 years of follow-up and remains on oral antibiotics.

Two proximal type I endoleaks were treated with proximal extensions. A further proximal type I endoleak was treated with a fenestrated extension incorporating the left common carotid artery origin. One distal type I endoleak was treated with a distal fenestrated extension graft incorporating the celiac and superior mesenteric arteries. A persistent type II endoleak from retrograde flow via the left subclavian artery was treated with glue embolization. A single type III endoleak at the modular joint of a TX2 device within a calcified aorta was treated with the placement of a large Palmaz stent (Cordis Endovascular, Great Lakes, NJ). All of these endoleaks resolved after the secondary procedure.

After 1 year of observation, an endoleak of unknown origin that occurred after the completion of an elephant trunk procedure was treated with proximal and middle graft extension pieces. The endoleak persists at the 2-year and 3-year follow up visits. It is visible only at the aneurysm margins on the delayed contrast CT images and has been considered a type II endoleak. The aneurysm sac size has remained stable.

Low-grade mesenteric ischemia developed in one patient after a four-vessel mesenteric bypass and total thoracoabdominal aortic coverage. The ischemia likely resulted from a compressed limb of the distal bifurcated device ipsilateral to the inflow to the gut. The patient was treated with the placement of a Palmaz stent (Corids Endovascular) within the kinked limb, which resolved the problem.

Two years after treatment of a proximal chronic dissection in an additional patient, the aortic segment distal to the endovascular repair demonstrated continued growth. He underwent open repair in which the distal aspect of the stentgraft was used to construct the proximal anastomosis of the thoracoabdominal repair.

Five additional secondary procedures were performed for complications resulting from the stent-graft surgery, including 3 common femoral access site issues, 1 brachial artery thromboses, and one groin hematoma evacuation.

Most patients had diminishing aneurysm size $\leq$12 months. Only one patient was noted to have increasing aneurysm size. This occurred in the setting of a proximal type I endoleak that was treated with a secondary procedure after the 1-year follow-up visit.

DISCUSSION

Ideally, a thoracic endovascular graft will be flexible enough to accommodate the requisit tortuosity of the arch, incorporate a fixation system that is secure both proximally and distally, seal within both straight and tortuous segments, be readily deliverable, and have favorable effects on the excluded region of the aorta. Additionally, delivery of the device would optimally not require the induction of hypotension or bradycardia and should be easily accomplished despite the proximity of pathology to the aortic valve in the setting of extreme tortuousity.

Unfortunately, such an optimal design does not yet exist. Specific problems that have been reported with the use of predicate designs included migration of both the proximal and distal fixation systems,[3] erosion of uncovered proximal stents through the aortic arch,[7] and component separation when modular thoracic grafts were used.[3,5] Similar problems have been described after implantation with other prostheses.[5,8,9] The devices described in this report has been designed to specifically address some of these concerns.

Table III. Results of treatment classified in terms of presenting pathology*

			Thoracic aneurysms		*Chronic dissections with aneurysm*	
		Overall	*A*‡	*B*‡	*A*‡	*Other*†
No. patients		100	64	17	15	4
Survival	30 days	93%	92%	100%	100%	50%
	12 mon	83%	81%	81%	100%	50%
	24 mon	77%	76%	70%	100%	50%
Secondary pocedures	Overall (mon)	15	7	5	2	1
Sac shrinkage	12 (n = 48)	52%	54%	38%	55%	50%
	24 (n = 24)	56%	58%	50%	55%	50%
Sac growth	12	1.6%	2.3%	0%	0%	0%
Migration	12	6.0%	6.3%	0%	11%	0%

*Survival numbers are calculated using Kaplan-Meier analyses. Sac shrinkage is based upon three-dimensional imaging analysis with the immediate postprocedure film establishing the baseline size, and a change in diameter being defined as >5 mm in either direction. Migration is defined as >10 mm movement and is based on centerline of flow measurement calculations from either the left common carotid artery or celiac artery.

†Includes 1 subclavian artery aneurysm, 1 aortobronchial fistula, 1 aortoesophageal fistula, and 1 thoracic aortic rupture.

‡In each category, group A refers to patients who were primarily treated with an endovascular graft. Group B patients required either an elephant trunk or visceral vessel bypass to create an adequate proximal or distal landing site.

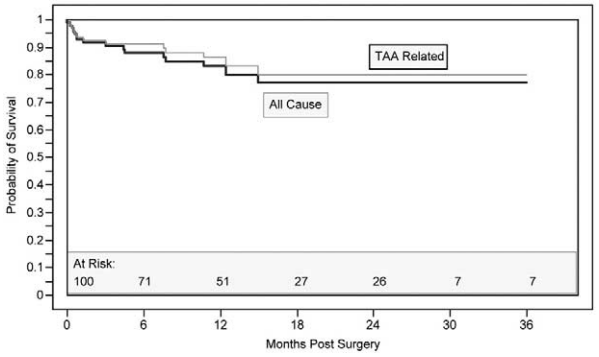

Fig 3. Kaplan-Meier analysis of mortality. Results are expressed in terms of all cause mortality and thoracic aneurysm repair related mortality. *TAA,* thoracic aortic aneurysm.

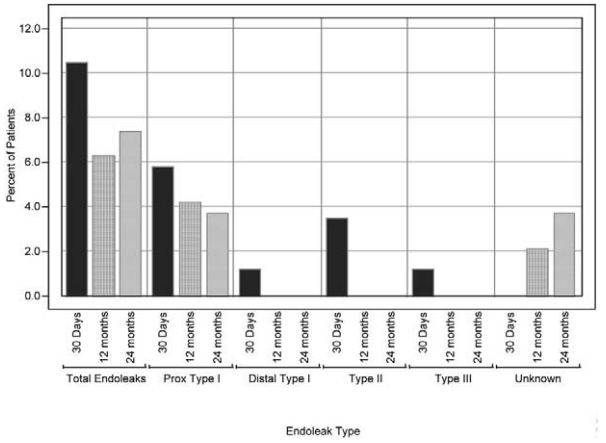

Fig 4. Type of endoleak and temporal incidence of endoleak for the combined experience (all pathologies, all device types).

The placement of caudal barbs on the proximal stent is intended to discourage distal migration of this stent in a manner similar to the Zenith abdominal aortic aneurysm device. The crainially oriented barbs on the distal stent are intended to prevent proximal migration of the distal stent and allow for accurate delivery in the region of the visceral vessels. Increased overlap within the two-piece design has been encouraged to minimize the risk of component separation and provide a degree of flexibility during the device deployment to allow for procedure-related alteration of aortic length (straightening of tortuous segments). Furthermore, the staged deployment of the proximal and distal fixation systems allows one to concentrate solely on how close the graft material is to the aortic branches without regard to the rest of the aorta.

Two thoracic devices are currently undergoing studies in the United States, and one was recently approved for use in thoracic aneurysms (TAG, W.L. Gore & Assoc, Flagstaff, Ariz), while all are commercially available in Europe and Australia including the Zenith, TAG and Talent devices (Medtronic AVE, Minneapolis, Minn). Although each device has merits, each has its faults.

The device described here requires the use of relatively long (17 to 22 mm) proximal and distal sealing stents. This precludes optimal flexibility and complicates sealing within tortuous segments such as the aortic arch. To overcome this, the sealing stent must be placed into a relatively straight aortic segment.

The delivery system resembles the Zenith abdominal device in that it handles tortuous iliac arteries nicely, but the sheath can kink in the setting of extreme arch angulation, making graft deployment difficult. This did not prevent treatment of any patients in this series and was later corrected with a new delivery system that incorporates braided technology and is markedly more flexible.

The desire to treat several types of thoracic pathology has outpaced the development or validation of devices used for unintended diseases. The obvious example is the use of

Table IV. All mortalities potentially associated with the procedure or device are listed

Categorization	*Cause of death*	*POD*	*Description*
<30 days	MI	17	Out of hospital ventricular tachycardia
	MI	18	In hospital
	MSOF	15	Ischemic perforation of stomach and gallbladder after intentional coverage of celiac artery
	MSOF	10	Distal embolization to mesenteric, renal and lower extremity, paraplegia
	Pneumonia	28	Suffered an embolic CVA, recovered most of neurologic function, died at rehabilitation facility
31-365 days	AAA rupture	14	Known 7-cm AAA scheduled for repair 1 month after thoracic repair
	AEF*	1	Compassionate-use treatment for bleeding AEF 8 years after an uncompleted elephant trunk procedure
	MSOF	40	Distal embolization to mesenteric and renal vasculature
	Pneumonia	93	Recovering from a procedure-induced thalamic infarct in a rehabilitation facility
	Sepsis	185	Developed a pancreatic fistula after a mesenteric bypass procedure preceding the endograft. Sepsis developed from the fistula 3 months after stent graft implantation
	Pneumonia†	215	Ventilator-dependent patient before endograft implant, pneumonia developed remote from procedure.
>365 days	MI	366	Suffered MI 1 day after a proximal extension graft placement
	Aortobronchial fistula	451	Endograft preceded by open AAA repair and visceral vessel bypass. Fistula noted on autopsy to be remote from endograft and bypass procedure in the distal segment of aneurysm

POD, Postoperative day; *MI,* myocardial infarction; *MSOF,* multisystem organ failure; *CVA,* cerebrovascular accident; *AAA,* abdominal aortic aneurysm; AEF, aortoesophageal fistula.

*An autopsy performed demonstrated the stent graft was in good position. The exsanguination was likely from continued intercostal perfusion.

†Preprocedure ventilator dependency with resultant pneumonia 6 months postprocedure while in pulmonary rehabilitation setting, possibly related to procedure.

thoracic endografts for aortic dissections. Although similarities exist in the location of the device placement in many circumstances, the treatment goals are entirely different, and the forces endoprostheses encounter after implantation are drastically diverse. For these reasons, we did not include any patients treated for acute aortic dissections and limited the use of this device to chronic dissections in the setting of aneurysms >5 cm in addition to patients with more traditional aneurysms. When treating the chronic dissections, we attempted to seal above and below the dissected lumen when possible, and extra-anatomic bypass procedures were frequently required. Overall, the series represents a relatively complex population where a little more than half of the patients had undergone aortic procedures before treatment with this endovascular graft.

Spinal cord ischemia has long been heralded as the Achilles heel of thoracic and thoracoabdominal aortic repair. The incidence of spinal cord ischemia in this series is not dissimilar to prior reports.[3,5,9,10] Although two cases of paraplegia were noted, only one was attributed to a pure intercostal coverage affect. Spinal cord drainage was used preoperatively in the setting of extensive aneurysms and in all patients with a prior aortic repair or with compromised hypogastric circulations. In addition, drainage was instituted in all patients with a postprocedure deficit, where the perfusion pressure was presumably increased by lowering the drain to 5 cm H_2O. This technique was applied more liberally earlier in our experience and more selectively in the later years. No adverse events were attributed to the spinal drainage catheters.

Strokes were uncommon. Two of the three events in this series occurred acutely during balloon inflation within the arch. Consequently, we are now reluctant to use a balloon in this region, and do so only in the setting of proximal endoleak or misaligned device.

The behavior of the device and aneurysm sac is critical to chart during the follow-up studies. However, unlike the abdominal aorta where severe tortuousity is a relative contraindication for repair, the thoracic aorta is inherently tortuous. Therefore, measurements pertaining to aneurysm size and device migration clearly must be peformed using 3D imaging and centerline of flow techniques. Aneurysm shrinkage was present in most patients, providing assurance that the natural history of the aortic disease is reversed.

Despite the belief that significant morphologic changes may be associated with component separation,[11,12] no component separations were observed in this series. Migration may occur as a result of loss of fixation system integrity, progression of aortic disease in terms of dilatation of fixation sites, or simply after continued exposure to the extreme hemodynamic forces present in the thoracic aorta. The crainially oriented distal barbs and caudal proximal barbs are intended to discourage migration.

Reporting standards have not been published defining migration for thoracic endoprostheses. Ultimately, the goal must be to have no migration; however, given the likelihood of measurement variation, a range must be established. We chose an absolute cutoff of 10 mm for the purposes of this report but continue to collect data with the hope of further defining when any observed migration may

become predictive of long-term graft instability. Overall, the migration rate in this series was low, despite most patients having >1 year of follow-up. The values reported unquestioningly underpredict the ultimate migration incidence. We did process all available imaging studies with meticulous analyses using 3D reconstruction and measurement techniques and used the left common carotid and celiac arteries as reference vessels.

It is more difficult to define a region of normal aorta surrounding a thoracic aorta than in the setting of infrarenal repair. Complete thoracic aortic coverage was not desirable for relatively focal aneurysms, and thus a calculated risk involving moderate coverage of the thoracic aorta in an effort to minimize the risk of paraplegia was undertaken. A conservative coverage policy in these patients would predict a potentially higher incidence of secondary interventions as a result of further degeneration of the proximal or distal thoracic aortic. This was not observed in this series; however, the follow-up duration is not likely long enough for the detection of late fixation site dilation.

Although this series was prospective with defined inclusion criteria, a degree of judgement was used during the patient selection process. Other devices (the W.L. Gore TAG and Medtronic Talent) were intermittently available during the patient accrual process. In general, patients were preferentially enrolled in prospective multicenter trials if they qualified for such. They were considered for this protocol if they did not meet multicenter trial inclusion criteria or no other trials were enrolling. Exceptions to this were made when, in the treating physicians judgement, one device would be more preferential than another given the anatomic situation and various device limitations. To add perspective to this issue, approximately 25 patients were enrolled in multicenter trials compared with the 100 patients in this study. Clearly, these factors preclude generalized, concurrent, device comparison studies and likely affect the results of each trial.

This device was associated with a high degree of technical success in a very complex patient population, which attests to its deliverability in both straight-forward and challenging anatomic situations. A comparitvely high rate of procedure-related mortality in contrast with the endovascular treatment of infrarenal aneurysms was noted; however, this correlates closely with the extreme patient population being treated. Endoleaks were uncommon (particularly type II endoleaks) and when present, frequently required treatment with the extension of the proximal or distal aspect of the graft. Favorable behavior of the aneurysm sac was noted in most patients through 24 months of follow-up, with only one patient exhibiting growth attributed to a type I endoleak. The sac behavior parallels that of the Zenith infrarenal device, and thus any patient exhibiting aneurysmal growth should be carefully evaluated. Migration was uncommon in the presence of active (barb) fixation systems in the absence of an uncovered proximal stent, and no device integrity issues have been noted.

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